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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,709	10/17/2003	Robert H. Harris	13095A	2201

7590 09/26/2005

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,709	HARRIS, ROBERT H.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21,25-34,56,63-67 and 73-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21,25-34,56,63-67 and 73-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Pursuant to the directives of the response filed 7/18/05, claims 20, 21, 25-28, 34, 63 have been amended, claims 22-24 and 52 cancelled, and claims 73-103 added. Claims 20, 21, 25-34, 56, 63-67, 73-103 are now pending.

Applicants' arguments filed 7/18/05 have been considered and found persuasive in part. The previously imposed prior art rejections are withdrawn.

. . . .

The following abbreviations are used hereinbelow:

"**EWG**" represents an electron-withdrawing group

"**EDG**" represents an electron-donating group

"**EWG/EDG**" signifies that a group may be either electron-donating, or electron- withdrawing

✦

35 U.S.C. §101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter or any new and useful improvement therof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 20, 21, 25-34, 56, 63-67, 73-103 are rejected under 35 USC §101 because the claimed invention is not supported by a well established utility.

As indicated previously, the claims are drawn to a method for "prophylaxis" of migraine headaches. This term implies that headaches can be prevented. The term implies a 100% success rate. Suppose that, for example, one of the claimed

compounds were administered to each of 1000 persons who had, in the past, shown a pronounced propensity for migraine headaches. If as a result of the administration, 999 of the patients never again developed a headache of any kind, and such a result would be wildly successful by any standard. But such a result would actually provide evidence that prevention had not been achieved. Applicants' data falls far short of the "bar" that would have to be overcome in demonstrating prevention or prophylaxis. It is suggested that the term at issue ("prophylaxis") be deleted.

In response, applicants have argued (page 19, line 1 of the response filed 7/18/05) that somewhere there exists a court opinion or statute which holds that in imposing a rejection for lack of utility or enablement, the examiner must prove that failure of the claimed invention is inevitable. However, applicants have declined to provide any authority for such a proposition. If applicants continue to believe that this is the standard, it would be helpful if applicants would cite not only the statute or court decision, but the exact passage as well. In reality, of course, there is no such statute or court decision. The examiner need not prove beyond all doubt that failure is inevitable. In the instant case, the standard which must be met by the examiner is actually quite low, since the issue raised (at this point) is not whether treatment of migraine headaches is enabled, but rather whether 100% of all migraine headaches within a given population of patients can be prevented. Note that the claim does not recite that the incidence of headaches will be reduced, or the probability of experiencing a headache will be reduced. Rather, the claims

encompass the assertion that 100% of all patients will circumvent the experience of migraine headache pain as a result of taking a dose (or several doses) of the compound. The issue then is the following: if one begins with the premise that a given compound is effective to "treat" migraine headaches (i.e., reduce the incidence or severity thereof), does it follow therefrom that every single patient who administers the compound will never get a migraine headache? Consider the following:

- Goldstein D. J. (*Cephalalgia : an International Journal of Headache* **17** (7) 785-90, 1997) discloses (last paragraph of the last page of the article) that "existing ...migraine therapies are not effective in treating every migraine for any specific individual, and are differentially effective..."

- Brandes Jan L (*Headache* **44** (6) 581-6, 2004) discloses (page 585, col 2) that an earlier study had found montelukast to be therapeutically effective in treating migraines. Brandes also conducted a study in which many of those receiving the compound reported efficacy in the treatment of their headaches. Yet the study also found that montelukast was clearly not effective in preventing headaches.

These references support the proposition that if one begins with the premise that a given compound is effective to "treat" migraine headaches, it does not follow therefrom that the compound will prevent headaches. The examiner has thus met his burden in raising doubt about the veracity of applicants' proposition.

Claims 20, 21, 25-34, 56, 63-67, 73-103 are also rejected under 35 USC §112 first paragraph. Specifically, since the claimed invention is not supported by a well-

established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

✦

Claims 25-28, 63, 74, 88, 89, 102 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites that R_2 and R_3 may be substituted with "an" EWG/EDG. Claim 22, upon which claim 25 depends, limit the EWG's and EDG's to specific substituents. Thus, claim 25 can be viewed as encompassing compounds that are not encompassed by claim 22. Accordingly, the claim dependence is improper. One option would be to cast claim 25 in independent form. The same issue applies in the case of claims 26, 27, 28, 63, 74, 88, 89, 102.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.